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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,052	06/29/2001	Frank J. Bunick	MCP-281	9476

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
05/03/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/896,052	BUNICK ET AL.	
	Examiner	Art Unit	
	S. TRAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date. _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/29/10 has been entered.

Claim Rejections - 35 USC § 103

Claims 1-3, 5-9, 11-13, 15, 17-19 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bealin-Kelly et al. US 6,432,441, in view of Bhardwaj et al. US 5,578,316 and Mackles US 4,260,596.

Bealin-Kelly teaches a throat drop composition comprising an aqueous filled center in the form of paste or gel (abstract; and column 2, lines 21-27). The gel or paste center filled comprising active agents having particle size of from about 1 μm to about 100 μm (column 3, lines 14-23). Active agents include analgesic (column 2, lines 28-34). The center filled is coated with a shell composed of chewing gum or hard or soft candy (column 4, lines 23-43).

Bealin-Kelly does not expressly teach the claimed particle size.

Bhardwaj teaches a palatable chewable tablet comprising drug particle having particle size from about 180-420 μm (column 2, lines 18-20). The tablet further

comprises binder such as gelatin (column 3, line 61). Bhardwaj further teaches drug includes acetaminophen (column 2, line 32).

Thus, it would have been obvious to one of ordinary skill in the art to optimize the throat drop composition of Bealin-Kelly to include drug particles having the claimed diameter in view of the teachings of Bhardwaj with the expectation of at least similar results. This is because Bhardwaj teaches drug particle having the claimed diameter is known in the art, because Bhardwaj teaches particles having the claimed size tend is more advantage over smaller particles size because smaller particles present problems in the coating process (column 2, lines 20-25).

Bealin-Kelly further does not teach the claimed ratio between the active agent and the shell. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In the present case, applicant has not shown that such ratio result in any unexpected and/or unusual result. Therefore, it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine suitable amount of active agent depends in the desirability of use.

Bealin-Kelly further does not expressly teach the claimed thickness of the edible shell.

Mackles teaches an edible unit dosage form comprising a liquid or gel center containing an active agent, and an outer edible shell having thickness generally in the range of about 0.5 to about 3.0 mm (abstract; Figs.; and column 2, lines 57-61). Thus, it would have been obvious to one of ordinary skill in the art to optimize the edible shell of Bealin-Kelly to have the thickness that falls within the claimed range. This is because Mackles teaches edible shell having the claimed thickness is useful for coating aqueous filled center, because Bealin-Kelly teaches an aqueous filled center, and because Bealin-Kelly teaches the desirability for preparing an edible coating such as chew gum or hard or soft candy.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buehler et al. EP 0950402A2, in view of Lee US 6,060,078, Bhardwaj et al. US 5,578,316, Silva et al. US 4,753,790, and Mackles US 4,260,596.

Buehler teaches a chewable pharmaceutical composition comprising a gelatin matrix that contains a pharmaceutically active agent (abstract). The matrix further comprises water, and mixture of hydrocolloids such as pectin (paragraphs 0012 and 0021). Active agent includes ibuprofen and acetaminophen (paragraph 0014 and examples).

Buehler does not teach the particle size of the active agent.

Bhardwaj teaches a palatable chewable tablet comprising drug particle having particle size from about 180-420 μm (column 2, lines 18-20). The tablet further

comprises binder such as gelatin (column 3, line 61). Bhardwaj further teaches drug includes acetaminophen (column 2, line 32).

Thus, it would have been obvious to one of ordinary skill in the art to optimize the chewable composition of Buehler to include active agent having the claimed particle diameter in view of the teachings of Bhardwaj to obtain the claimed invention. This is because Bhardwaj teaches drug particle having the claimed diameter is known in the art, because Bhardwaj teaches particles having the claimed size tend is more advantage over smaller particles size (column 2, lines 20-25), because Bhardwaj teaches that particles having the claimed diameter is useful for formulating extremely palatable chewable tablet (column 3, lines 43-51), and because Buehler teaches the desirability for obtaining a chewable composition with enhanced palatable properties.

Buehler further does not teach the shell encasing the chewable matrix.

Silva discloses a coated comestible having a hard outer shell (abstract). The dosage form comprises a core that is coated with the shell, where the core can be in various forms, such as gums, candies, jellies, and pills or tablets used for medicinal purposes (column 3, lines 20-32). In the examples provided, the final coated products have an outer shell in a quantity that ranges from approximately 20% to 40% by weight of the product (See Examples I to V; and Tables 5, 9, 13, 17 and 18).

Mackles teaches an edible unit dosage form having an outer shell and a liquid or gel center containing an active agent (See Abstract; and Figures). Although the thickness of the shell may vary, it is generally in the range of about 0.5 to about 3.0 mm (See Column 2, Lines 57-61).

Thus, it would have been obvious to one of ordinary skill in the art to combine the teachings of Buehler, Silva and Mackles into the objects of the instant application. This is because Silva teaches the use of a coating to provide good appearance, good texture, and a welcome contribution to the art of chewable dosage form (column 2, lines 16-30), because Mackles teaches the use of shell to protect the core from the storage atmosphere (abstract; and columns 1-2), because Silva and Mackles teach that the use of shell to protect a chewable tablet core is well known in the art, and because Buehler teaches the desirability for obtaining a suitable chewable tablet useful for the art.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee US 6,060,078, in view of Bhardwaj et al. US 5,578,316, Siva et al. US 4,753,790, and Mackles US 4,260,596.

Lee teaches a chewable pharmaceutical dosage form comprising of a core containing an active ingredient, and an outer layer (See Figure 2). The dosage form demonstrates improved organoleptic properties when chewed, such as taste (See column 1, lines 47-52). The core may be in the form of a jelly, with the base of the jelly selected from a group that includes pectin (See column 2, lines 29-33). In addition, gelatin may be used in either the core or outer layer to maintain hardness and extension property in the dosage form (See column 2, lines 59-61). The outer layer may take a variety of forms, including hard candy (See column 2, lines 34-42). Acetaminophen is listed as a possible active ingredient in the core (See Column 2, Lines 9-18). In addition, Lee contains what the examiner will interpret as an enabling disclosure of a

dosage form with a unitary core (See Figure 2; and MPEP § 2125). The disclosed invention has the advantage of having an improved chewing property, which the examiner broadly interprets as having a texture masking property, in addition to having a taste masking property (See Column 3, Lines 53-58).

Lee does not explicitly teach the claimed particle size.

Bhardwaj teaches a palatable chewable tablet comprising drug particle having particle size from about 180-420 µm (column 2, lines 18-20). The tablet further comprises binder such as gelatin (column 3, line 61). Bhardwaj further teaches drug includes acetaminophen (column 2, line 32).

Thus, it would have been obvious to one of ordinary skill in the art to optimize the throat drop composition of Lee to include drug particles having the claimed diameter in view of the teachings of Bhardwaj to obtain the claimed invention. This is because Bhardwaj teaches drug particle having the claimed diameter is known in the art, because Bhardwaj teaches particles having the claimed size tend is more advantage over smaller particles size because smaller particles present problems in the coating process (column 2, lines 20-25).

Lee further does not teach the amount and ratio of the shell.

The Silva *et al.* patent discloses a coated comestible having a hard outer shell (See Abstract). The dosage form comprises a core that is coated with the shell, where the core can be in various forms, such as gums, candies, jellies, and pills or tablets used for medicinal purposes (See Column 3, Lines 20-32). In the examples provided, the final coated products have an outer shell in a quantity that ranges from

approximately 20% to 40% by weight of the product (See Examples I to V; and Tables 5, 9, 13, 17 and 18).

The Mackles patent teaches an edible unit dosage form having an outer shell and a liquid or gel center containing an active agent (See Abstract; and Figures). Although the thickness of the shell may vary, it is generally in the range of about 0.5 to about 3.0 mm (See Column 2, Lines 57-61).

It would be obvious to one of ordinary skill in the art to combine the teachings of Lee, Silva *et al.,* and Mackles into the objects of the instant application. Both the Lee and Mehta patents deal with the administrations of drugs in pharmaceutical compositions with improved organoleptic properties. Therefore, one of ordinary skill would be motivated to incorporate the microcapsules disclosed in Mehta into the dosage form of Lee in order to provide a pharmaceutical dosage form wherein the active ingredient is further taste-masked without an undue delay on the release of the drug. As such, it is the position of the examiner that one of ordinary skill in the art could combine the disclosures of the prior art with a reasonable expectation of success.

Response to Arguments

Applicant's arguments filed 03/29/10 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615